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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,514	04/30/2001	K. Roger Aoki	D2929CON	3428

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EXAMINER
FORD, VANESSA L

ART UNIT	PAPER NUMBER
1645	19

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/845,514	AOKI ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 17-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 17-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *11* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Upon further review and reconsideration, the finality of the rejection of the last Office Action, Paper No. 10 is withdrawn.

2. Applicant's response received March 13, 2003 is acknowledged.

Rejections Withdrawn

3. In view of Applicant's amendment and response, the following rejections are withdrawn:

a) Rejection of claims 1-4 and 6-9 under 35 U.S.C. 102(e), pages 2-5 of the previous Office action is withdrawn in view of Applicant's response.

b) Rejection of claims 17-20 and 22-28 under 35 U.S.C. 102(e), pages 4-5 of the previous Office action is withdrawn in view of Applicant's response.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9 and 17-26 recite, "... to control a duration of therapeutic activity of the neurotoxins". It is unclear as to what the applicant is referring? Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 6, 17, 22 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ludlow et al *(New England Journal of Medicine, Jan. 30, 1992)* in view of Schantz et al *(Microbiological Reviews, March 1992, p. 80-99).*

Claims 1, 6, 17, 22 and 26-27 are drawn to a method of treating a patient suffering from a neuromuscular disorder or condition said method comprising the steps of administering simultaneously to the patient a therapeutically effective amount of at least two neurotoxins selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G of each selected neurotoxin being selected to control a duration of therapeutic activity of the administered neurotoxins and a composition comprising at least two neurotoxins selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.

Ludlow et al teach the use of a composition comprising Botulinum toxin type F to treat Torticollis, (a neuromuscular disorder or condition).

Ludlow et al do not teach using a composition comprising at least two neurotoxins selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G to treat patients suffering from torticollis.

Schantz et al teach that Botulinum toxin A can provide profound symptomatic relief from humans suffering from a wide variety of disorders characterized by involuntary movements of muscle groups (including torticollis) (page 83, 2nd column and page 84, Table 2).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use a combination of Botulinum toxin type A as taught by Schantz et al and Botulinum toxin type F as taught by Ludlow et al in the method of treating patients against torticollis because Ludlow et al has demonstrated that Botulinum toxin F can be used to treat patients suffering from neuromuscular disorders or conditions and Schantz et has taught that Botulinum toxin A can provide profound symptomatic relief from patients suffering from a wide variety of neuromuscular disorders or conditions.

In re Nilssen (7 USPQ 2d 1500) states:

> ...The board attributes to the "hypothetical person" knowledge of all prior art in the filed of the inventor's endeavor and of the prior art solutions for a common problem even if outside that field.
>
> We reject that recommendation as contrary to our precedent, which holds that for the purpose of combining references, those references need not explicitly suggest combining teachings, much less specific references.

Therefore, "it is *prima facie* obvious to combine two compositions each of which is taught in the art to be used for the very same purpose: idea of combining them flows logically from their having been individually taught in the prior art".

6. Claims 1, 6, 17, 22 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ludlow et al *(The New England Journal of Medicine, Jan. 30, 1992)* in view of Tsui et al *(The Lancet, August 2, 1986).*

Claims 1, 6, 17, 22 and 26-27 are drawn to a method of treating a patient suffering from a neuromuscular disorder or condition said method comprising the steps of administering simultaneously to the patient a therapeutically effective amount of at least two neurotoxins selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G of each selected neurotoxin being selected to control a duration of therapeutic activity of the administered neurotoxins and a composition comprising at least two neurotoxins selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.

Ludlow et al teach the use of a composition comprising Botulinum toxin type F in to treat torticollis.

Ludlow et al do not teach using a composition comprising at least two neurotoxins selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.

Tsui et al teach a composition comprising botulinum toxin A and normal saline used to treat spasmodic torticollis, (neuromuscular disorder or condition) (page 245, 2nd column).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use a composition comprising a combination of Botulinum toxin type A as taught by Tsui et al and Botulinum toxin type F as taught by

Ludlow et al in the method of treating patients against torticollis because Ludlow et al has demonstrated that Botulinum toxin F can be used to treat patients suffering from torticollis and Tsui et al has demonstrated the efficacy and safety in the treatment of spasmodic torticollis using compositions comprising Botulinum toxin A (page 246, 2nd column).

In re Nilssen (7 USPQ 2d 1500) states:

> ...The board attributes to the "hypothetical person" knowledge of all prior art in the filed of the inventor's endeavor and of the prior art solutions for a common problem even if outside that field.
>
> We reject that recommendation as contrary to our precedent which holds that for the purpose of combining references, those references need not explicitly suggest combining teachings, much less specific references.

Therefore, "it is *prima facie* obvious to combine two compositions each of which is taught in the art to be used for the very same purpose: idea of combining them flows logically from their having been individually taught in the prior art".

7. Claims 1-9 and 17-29 rejected under 35 U.S.C. 103(a) as being unpatentable over Ludlow et al and Schantz et al as applied to claims 1, 6, 17, 22 and 26-27 above, and further in view of Sugiyama *(Microbiological Reviews September 1980, p. 419-448).*

Claims 1-9 and 17-29 are drawn to a method of treating a patient suffering from a neuromuscular disorder or condition said method comprising the steps of administering simultaneously to the patient a therapeutically effective amount of at least two neurotoxins selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G of each selected neurotoxin being selected to control a duration of therapeutic

activity of the administered neurotoxins and a composition comprising at least two neurotoxins selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.

The combination of Ludlow et al and Schantz et al as set forth *supra* differs by not teaching the combination of A and B or A and E.

Sugiyama teaches that are seven (A-G) known serotypes of botulinum toxin that have been isolated and characterized. Sugiyama teaches antigenically different neurotoxins have a common and unique pharmacological action (page 427, 2nd column).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute any of the B,C,D,E or G for the "F" neurotoxin in the combination of Ludlow et al and Schantz et al as combined *supra* because Sugiyama teaches that these antigenically different neurotoxins have a common and unique pharmacological action and the substitution of the one for the other would be readily expected to work given that two of the individual neurotoxins have been individually shown to be effective for the treatment of torticollis.

8. Claims 1, 6, 17, 22 and 26-27 rejected under 35 U.S.C. 103(a) as being unpatentable over Ludlow et al and Schantz et al as applied to claims 1, 6, 17, 22 and 26-27 and further in view of Sugiyama *(Microbiological Reviews September 1980, p. 419-448).*

Claims 1, 6, 17, 22 and 26-27 are drawn to a method of treating a patient suffering from a neuromuscular disorder or condition said method comprising the steps of administering simultaneously to the patient a therapeutically effective amount of at least two neurotoxins selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G of each selected neurotoxin being selected to control a duration of therapeutic activity of the administered neurotoxins and a composition comprising at least two neurotoxins selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.

The combination of Ludlow et al and Schantz et al as set forth *supra* differs by not teaching the combination of more than 2 or all botulinum neurotoxins.

Sugiyama teaches that are seven (A-G) known serotypes of botulinum toxin that have been isolated and characterized. Sugiyama teaches antigenically different neurotoxins have a common and unique pharmacological action (page 427, 2nd column).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to add any one of or all of the B,C,D,E or G botulinum toxins to the "A and F" neurotoxin combination of Ludlow et al and Schantz et al as combined *supra* because Sugiyama teaches that these antigenically different neurotoxins have a common and unique pharmacological action and the addition of any or all of these neurotoxins would be readily expected to work given that two of the individual neurotoxins have been individually shown to be effective for the treatment of torticollis.

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
June 26, 2003

PATRICIA A. DUFFY
PRIMARY EXAMINER